

Call your doctor or get medical care right away if you have any of the following symptoms that might indicate serious side effects.

Infection:

- Fever
- Chills
- Unusual sweating
- Feeling unwell or feeling more tired than normal
- Throwing up (vomiting) or feeling like you're going to throw up (nausea)
- Diarrhoea
- Stomach pain
- Not feeling hungry the way you usually do (loss of appetite)
- Losing weight
- Coughing or coughing up blood or mucus
- Feeling like you can't catch your breath (shortness of breath)
- Problems peeing (urinating)
- Non-healing sores and wounds on your skin
- Sore muscles
- Problems with your teeth or gums

Cancer:

- Night sweats
- Swollen glands in your neck, armpits, groin, or other areas
- Weight loss
- New skin lesions or a change in skin lesions (such as moles or freckles) you already have
- Severe itchiness that cannot be explained

Nervous system problems:

- Feeling numbness or tingling anywhere in your body
- Changes in vision
- Muscle weakness
- Dizziness

Tell your doctor about any unusual symptoms that you have during treatment. These are not all of the possible symptoms of these side effects.

Information for you and healthcare professionals involved in your care

Your name: _____

Your doctor's name
(who prescribed HUKYNDRA): _____

Your doctor's telephone number: _____

Date of your first HUKYNDRA injection: _____

Date of your last HUKYNDRA injection
if your treatment has finished: _____

Dose of HUKYNDRA: _____

Tuberculosis tests and treatment

Please record the date and results of your last screening for TB below:

Tuberculin test: _____

Chest X-ray: _____

Have you ever tested positive for tuberculosis?

Yes No

Did you receive treatment for having a positive tuberculosis test?

Yes No

How long were you treated for tuberculosis? _____

Information about any tuberculosis tests or treatment you have had:

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

Hukyndra[®]
adalimumab

Patient Reminder Card for Adults

This card has important safety information about HUKYNDRA

Please be sure to:

- Show this card to all of your doctors and other healthcare providers. This is so they know you are taking HUKYNDRA.
- Keep this card with you at all times while you are taking HUKYNDRA and for 5 months after your last injection of HUKYNDRA.
- In the notes section on the back of this card, write down information about any tuberculosis tests or treatment you have had.

The possible side effects listed on this card are not the only possible side effects of HUKYNDRA. For more comprehensive information, please read the HUKYNDRA package leaflet included in the HUKYNDRA package or available on www.hpra.ie, or talk with your doctor.

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What is HUKYNDRA?

The immune system normally protects the body from infection, but in some disease states (autoimmune diseases) this system doesn't work the way it should. HUKYNDRA is a medicine that is used to treat certain autoimmune diseases. The purpose of this card is to inform you about some of the side effects associated with HUKYNDRA.

Side effects that could happen with HUKYNDRA include:

- Infections (including tuberculosis)
- Cancer
- Problems with your nervous system

These are not all of the possible side effects of HUKYNDRA.

Certain vaccines may cause infections and should not be given while receiving HUKYNDRA. Please check with your doctor before you receive any vaccines.

What should I know before I start treatment with HUKYNDRA?

The benefits and risks of taking HUKYNDRA vary from person to person. Before starting treatment with HUKYNDRA, you should talk with your doctor about the benefits and risks for you. Before starting treatment, you should tell your doctor:

- About any health problems you have
- About any medicines you take (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
- If you:
 - Have an infection or symptoms of an infection (such as fever, non-healing sores, wounds, feeling tired, dental problems)
 - Have tuberculosis currently or have had it in the past or have been in close contact with someone who has tuberculosis

- Have cancer or have had it in the past
- Ever feel any numbness or tingling
- Have a problem that affects your nervous system, such as multiple sclerosis
- Reside or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic

Your doctor will check you for signs and symptoms of tuberculosis before you start treatment with HUKYNDRA. This will include a medical evaluation including your medical history and appropriate screening tests (for example chest x-ray and a tuberculin test). The conduct and results of these tests should be recorded on this card. You may need to be treated for tuberculosis before you start treatment with HUKYNDRA.

Vaccination advice

Certain vaccines may cause infections and should not be given while receiving HUKYNDRA. Please check with your doctor before you receive any vaccines.

If you received HUKYNDRA while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your HUKYNDRA use during your pregnancy so they can decide when your baby should receive any vaccine.

What should I do during my treatment with HUKYNDRA?

During your treatment, you should:

- Keep your doctor informed about how HUKYNDRA is working for you.
- Call your doctor right away about any side effects or unusual symptoms you have. Your doctor may be able to help you manage the side effects and stop them from getting worse.
 - If you do have a side effect, your doctor will decide if you should keep taking HUKYNDRA.

- Tell your doctor about any side effects you have up to 4 months after your last injection of HUKYNDRA. This is because side effects can happen after your last dose of HUKYNDRA.
- Tell your doctor about:
 - Any new medical conditions that you have
 - New medicines you are taking (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
 - Any surgery or operation that you are having

Some people taking HUKYNDRA may get serious side effects, including:

Infections — People treated with HUKYNDRA are more likely to get infections and, when they do, the infections are more severe. This risk may increase if you have problems with your lungs or if you are over 65 years of age. Some of these infections are relatively minor, such as a common cold. Others are more serious and potentially fatal, such as tuberculosis.

Cancer — If you take HUKYNDRA, the risk of getting lymphoma (a cancer that affects the lymph system), leukaemia (a cancer that affects the blood and bone marrow) or other cancers may increase.

On rare occasions, an uncommon and severe type of lymphoma, has been seen in patients taking HUKYNDRA. Some of those patients were also treated with azathioprine or 6-mercaptopurine.

There have been cases of cancers, other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

Cases of non-melanoma skin cancer have also been observed in patients taking HUKYNDRA.

Nervous system problems — Some people treated with HUKYNDRA can develop new or worsening nervous system problems. This includes multiple sclerosis.